Remarks/Arguments:

Preliminary Matters

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98 and 112-123 are pending. Claims 1, 8-12, 15, 16, 23-27, 29-31, 36-39, 41, 42, 60-65, 68-70, 77-81, 85, 86, 91-94, 98 and 120 are herein amended. Applicants submit that no new matter has been added.

Claim Objection

Claim 120 is objected to as unclear. Applicants have amended claim 120 as suggested by the examiner and respectfully request withdrawal of such objection.

35 U.S.C. § 112

Claims 8-13, 15, 23-28, 30, 36-40, 42, 61-66, 69, 77-82, 85, 91-95 and 98 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for including the trademarks TRUEGRID, MIMICS, DYNA3D, NIKE3D or GRIZ. Claims 13, 28, 40, 66, 82 and 95 have been canceled. The objected to trademarks/trade names have been deleted from the remaining claims and replaced with generic descriptions corresponding to the descriptions set forth in the specification. Reconsideration of these claims is respectfully requested.

Claims 12-13, 27-28, 39-40, 65-66, 81-82 and 94-95 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for reciting equations that render it impossible to determine the meets and bounds of the claimed invention. Claims 13, 28, 40, 66, 82 and 95 have been canceled. With respect to claims 12, 27, 39, 65, 81 and 94, it is respectfully submitted that the claims are not indefinite. As explained in the specification, the present invention may be utilized with various devices in various applications. As such, the specific material parameters associated with the device and application may vary. The specification references on page 20 multiple articles which provide material parameters for TPEG applications. These articles provide examples of parameters that may be utilized, but the invention is not limited to such parameters. Each of these claims provides a specific equation and the specification explains at pages 19-29 the derivation, implementation and advantages of the claimed equations. Reconsideration of these claims is respectfully requested.

35 U.S.C. § 102

Claims 1-3, 16-18, 31, 32, 54, 56, 70, 72, 86, 113, 115 and 117-119 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,594,651 to St. Ville. Applicants respectfully traverse the rejection of these claims and respectfully submit that these claims are patentable over St. Ville for at least the reasons set forth below.

Independent claim 1 recites features that are neither disclosed nor suggested by St. Ville, namely:

> A system for analyzing medical devices comprising:
>
> a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature(s);
>
> a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and *generates a finite element model or mesh based on both of said geometric model of said anatomical feature(s) and said geometric model of said medical device*; and
>
> a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.*

St. Ville fails to disclose or suggest, at least, a mesh generator that *generates a finite element model or mesh based on both of said geometric model of said anatomical feature(s) and said geometric model of said medical device* and a stress/strain/deformation analyzer that *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.* St. Ville discloses a method of manufacturing objects based on standard forces or fields applied thereto.

Nowhere does St. Ville teach or suggest generating a finite element model or mesh based on both a geometric model of an anatomical feature and a geometric model of a medical device. Instead, St. Ville only teaches generating a finite element model of the object to be manufactured. St. Ville discusses two exemplary objects to be manufactured, namely, a golf club shaft and a composite replacement hip. The disclosure relating to the composite replacement hip is cited as teaching the generation of a finite element model or mesh based on

both a geometric model of an anatomical feature and a geometric model of a medical device. Specifically, St. Ville column 9, lines 31-33 is cited as teaching that "the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip . . . ." However, such discussion is limited to the generation a geometric model of the "object to be manufactured", not of an anatomical feature to be analyzed in conjunction with the medical device. The discussion of X-raying a cadaveric hip is included in the explanation of St. Ville step **22**, namely, "computer aided design is used to geometrically model **the object to be manufactured**." column 8, lines 58-59 (emphasis added). After the geometric model of the object to be manufactured is generated, perhaps by X-raying a cadaveric hip, St. Ville proceeds to step **23** wherein, "a finite element model of **the object** is generated using the finite element method." column 9, lines 39-40 (emphasis added).

Figure 6 is also cited as depicting "an anatomical feature (bone structure) and medical device (prosthetic hip joint)." Applicants respectfully submit that Figure 6 does not depict an anatomical feature, but instead only depicts the object to be manufactured, namely, the composite replacement hip. St. Ville explains at column 12, lines 48-55 the manufacture of the component labeled 601, 602 and 603. As explained therein,

> [f]or example, in the case of the prosthetic hip, regions of both high and low stiffness are required. Using the geometric model and the extracted material property coefficients, the manufacturing process and specifically, the tightness of the weave, can be controlled to provide a region of high stiffness (e.g., the region defined by element 601 in Fig. 6) and a region of low stiffness (e.g., the region defined by element 603 in Fig. 6).

All of the components illustrated in Figure 6 are components of the object to be manufactured. St. Ville fails to teach or suggest a mesh generator that generates a finite element model or mesh based on both of said geometric model of said anatomical feature(s) and said geometric model of said medical device.

Furthermore, St. Ville only teaches applying static force values to the object to be manufactured and does not teach or suggest simulating an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device. As explained at column 16, lines 49-58,

> The loads of walking, rising from a chair, climbing stairs, etc. are defined. These loads are used to define the forces at the nodes of the finite element model. These stiffness properties and loads **are known quantities which have been**

published in numerous journals, e.g., Hodge et al., Contact Pressures in the Human Hip Joint Measured In Vivo, Proc. Natl. Acad. Sci. USA, 83 2879-2883 (1986); Fung, Biomechanics, Mechanical Properties of Human Tissue, Springer-Verlag, New York (1981).

(emphasis added). The forces that are input are static figures, independent of the configuration of any specific anatomical feature(s) associated with the composite replacement hip. There is no teaching or suggestion of a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.

For at least the foregoing reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 1 is condition for allowance. Claims 2–12, 14, 15, 112 and 113 are dependent upon claim 1, and therefore, should also be allowed for the reasons urged with respect to claim 1. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 16 recites

A system for analyzing a medical device comprising:

a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of a particular individual and generates a geometric model of said anatomical feature(s);

a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and *generates a finite element model or mesh based on both said geometric model of said anatomical feature(s) and said geometric model of said medical device*; and

a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device*.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a mesh generator that *generates a finite element model or mesh based on both*

said geometric model of said anatomical feature(s) and said geometric model of said medical device and a stress/strain/deformation analyzer that *simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformation of said medical device*. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 16 is condition for allowance. Claims 17-27, 29, 30, 114 and 115 are dependent upon claim 16, and therefore, should also be allowed for the reasons urged with respect to claim 16. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 31 recites

> A system for analyzing a medical device comprising:
>
> a mesh generator that receives a geometric model of an *in vitro* anatomical feature and a geometric model of a medical device, and *generates a finite element model or mesh based on both said geometric model of said in vitro anatomical feature and said geometric model of said medical device*; and
>
> a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said *in vitro* anatomical feature and said medical device, load data on said *in vitro* anatomical feature and/or said medical device and *simulates an interaction between said in vitro anatomical feature and said medical device to determine the predicted stresses, strains, and deformations of said medical device*.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a mesh generator that *generates a finite element model or mesh based on both said geometric model of said in vitro anatomical feature and said geometric model of said medical device* and a stress/strain/deformation analyzer that *simulates an interaction between said in vitro anatomical feature and said medical device to determine the predicted stresses, strains, and deformations of said medical device*. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 31 is condition for allowance. Claims 32-39, 41, 42, 116 and 117 are dependent upon claim 31, and therefore, should also be allowed for the reasons urged with respect to claim 31. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 54 recites

A computer method for analyzing a medical device comprising:

acquiring three-dimensional volumetric data of at least one anatomical feature;

generating a geometric model of said anatomical feature(s);

receiving data representing a geometric model of a candidate medical device design;

receiving said geometric model of said anatomical feature(s);

generating a finite element model or mesh based on both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said candidate medical device design and said anatomical feature(s); and

simulating an interaction between said anatomical feature(s) and said candidate medical device design to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a computer method for analyzing a medical device comprising *generating a finite element model or mesh based on both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device design* and *simulating an interaction between said anatomical feature(s) and said candidate medical device design to determine the predicted stresses, strains, and deformation of said candidate medical device design by said load data*. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 54 is condition for allowance. Claims 55-65, 67-69 and 118 are dependent upon claim 54, and therefore, should also be allowed for the reasons urged with respect to claim 54. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 70 recites

A method for analyzing a medical device comprising:

acquiring three-dimensional volumetric data of at least one anatomical feature of a particular individual;

generating a geometric model of said anatomical feature(s);

receiving a geometric model of a candidate medical device;

receiving said geometric model of said anatomical feature(s);

generating a finite element model or mesh based on both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device;

receiving material properties of said anatomical feature(s) and said candidate medical device;

receiving load data imposed on said anatomical feature(s) and said candidate medical device; and

simulating an interaction between said anatomical feature(s) and said candidate medical device to determine the predicted dynamic or quasi-static stresses, strains, and deformations of said candidate medical device.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a method for analyzing a medical device comprising *generating a finite element model or mesh based on both said geometric model of said anatomical feature(s) and said geometric model of said candidate medical device* and *simulating an interaction between said anatomical feature(s) and said candidate medical device to determine the predicted dynamic or quasi-static stresses, strains, and deformations of said candidate medical device*. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 70 is condition for allowance. Claims 71-81 and 83-85 are dependent upon claim 70, and therefore, should also be allowed for the reasons urged with respect to claim 70. For all of these reasons, reconsideration of these claims is respectfully requested.

Independent claim 86 recites

A computer method for analyzing a medical device comprising:

receiving data representing a geometric model of at least one *in vitro* anatomical feature and a geometric model of a candidate medical device design;

generating a finite element model or mesh based on both said geometric model of said in vitro anatomical feature(s) and said geometric model of said candidate medical device design;

receiving material properties of said *in vitro* anatomical feature(s) and said candidate medical device design;

receiving load data imposed on said *in vitro* anatomical feature(s) and said candidate medical device design; and

simulating an interaction between said in vitro anatomical feature(s) and said candidate medical device to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data.

As discussed above in conjunction with claim 1, St. Ville neither discloses nor suggests a computer method for analyzing a medical device comprising *generating a finite element model or mesh based on both said geometric model of said in vitro anatomical feature(s) and said geometric model of said candidate medical device design* and *simulating an interaction between said in vitro anatomical feature(s) and said candidate medical device to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data*. For at least these reasons, St. Ville fails to disclose or suggest each and every element of Applicants' claimed invention. Applicants respectfully submit that independent claim 86 is condition for allowance. Claims 87-94, 96-98 and 119-123 are dependent upon claim 86, and therefore, should also be allowed for the reasons urged with respect to claim 86. For all of these reasons, reconsideration of these claims is respectfully requested.

35 U.S.C. § 103

Claims 4, 19, 57 and 73 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of U.S. Patent No. 5,880,976 to DiGioia III et al. Claims 5-7, 20-22, 33-35, 58-60, 74-76 and 88-90 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "A Finite Element Treatment of the In-Vivo Loading Conditions of NiTi Vascular Stent and Graft Structures" by F. Whitcher. Claims 8, 23, 61

and 77 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Automated Mesh Generation of an Arterial Bifurcation Based Upon *In Vivo* MR Images" by Seung Lee et al. Claims 9, 24, 36, 62, 78 and 91 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Finite Element Analysis of Human Joints" by P-L. Bossart and K. Hollerbach. Claims 10-13, 25-28, 37-40, 63-67, 79-83, 92-96, 112, 114 and 116 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin. Claims 14-15, 29-30, 41-42, 68-69, 84-85 and 97-98 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey. Claims 55, 71, 87 and 120-123 stand rejected under 35 U.S.C. § 103 as unpatentable over St. Ville in view of "Failure of All-ceramic Fixed Partial Dentures *in vitro* and *in vivo*: Analysis and Modeling" by J.R. Kelly, J.A. Tesk and J.A. Sorensen.

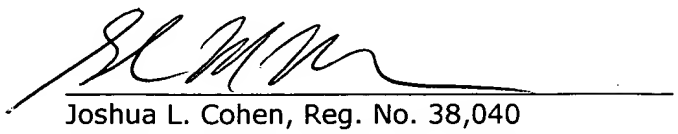
None of these cited references overcome the shortcomings of St. Ville as discussed above in connection with the independent claims. Each of the dependent claims should be allowable for at least its dependence from a respective allowable independent claim.

Conclusion

In view of the amendments and points of distinction set forth above, Applicants contend that the above-identified application is in condition for allowance, which action is respectfully requested.

If the examiner believes an interview, either telephonic or in person, will advance the prosecution of this matter, it is respectfully requested that the examiner contact the undersigned to arrange the same.

Respectfully submitted,



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